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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/758,902	DAVID ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 8-14-07 has been entered into the record. Claims 19 and 20 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 19 and 20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the Amendment to claim 20.

Reinstated Claim Rejections - Based on Amendment

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991).

This is a reinstatement of the rejection of record in the Office Action mailed 11-28-05 and maintained in the Office Action mailed 7-31-06.

Seifert teaches the use of a saponin adjuvant in the formulation of a multivalent clostridial vaccine using toxins of apparently different strains of Clostridial pathogens for the purposes of obtaining enhanced protective immune responses in a host. Seifert teach that the group has isolated three local pathogens from anaerobic infections and these pathogens are used for producing the anatoxin. The anatoxin from the three pathogens are toxoided with formalized sodium chloride solution and the toxoids are purified and concentrated. The toxoid vaccine is mixed with anthrax spores in saponin and

administered intracutaneously at a dose of 0.2 ml/animal, twice at an interval of 4 weeks. The vaccine provided for a marked protective effect (see page 2). Seifert et al differ by not providing for the addition of antigens from a respiratory virus and multiple serotypes/species.

Geresi et al teach the formulation of multivalent clostridial vaccine compositions Clostridium perfringens antigens (C and D-type toxins: different serotypes) and tetanus toxoid (different species), which also comprise a viral antigen (see page 38).

Farmers and Consumers Market Bulletin disclose a clostridial vaccine composition which comprises a viral immunogen from influenza, equine viral rhinopneumonitis, strangles and teaches the annual vaccination with the multivalent vaccine reduces the threat of infection from both the bacterium and the virus.

Kensil et al show the use of a saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprises a viral antigen. Kensil establishes the adjuvant activity of saponin is effective for viruses.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the Seifert vaccine by adding any desired additional clostridial components as taught by Geresi or Farmers and Consumers Market Bulletin and include a respiratory viral antigen as taught by Farmers and Consumers Market Bulletin because Geresi and Farmers and Consumers Market Bulletin teach that it is conventional to combine the multivalent clostridial vaccine with viral components and both Seifert and Kensil teach the use of saponin as an effective adjuvant for the enhancement of an immune response with either a clostridial or viral antigen respectively the combined vaccine would provide the advantage of reduced time and cost for administering multiple vaccines to farm/ranch animals. Absent unexpected results, one of skill in the art would expect the modified composition to protect from infection because the saponin adjuvant was effective to generate protective immunity in cattle and that

similar compositions with different adjuvants were also effective to generate protective immunity.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as applied to claim 20 above further in view of Green et al (The Veterinary Record, 120:435-439, 1987).

This is a reinstatement of the rejection of record in the Office Action mailed 11-28-05 and maintained in the Office Action mailed 7-31-06.

The teachings of Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as combined are set forth above. The teachings differ by not explicitly combining immunogens from six or more species or serotypes of *Clostridium*.

Green et al teach the formulation of a multi-valent clostridial vaccine for the purposes of stimulating a protective immune response against multiple serotypes and species of this pathogen. Green et al teach three known commercially available vaccines comprising at least 7 different serotypes/species of Clostridium for protection from infection (Tasvax, Heptavac, Covexin) page 435, column 2, Table 1.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the composition as combined *supra* by adding the other known individual clostridial vaccine toxoid components of Green et al (i.e. *C. perfringens* (serotype D), *C. septicum, C. novi, C. haemolyticum and C. chauveoi*) because

combined vaccines were commercially available and known to be effective for broad protection for a variety of pathogens in farm animals. Given the demonstrated efficacy and commercial availability of the 7- and 8- way combination vaccines, the combination as combined would be expected to be effective to protect from infection.

Status of Claims

Claims 19 and 20 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting Supervisor, Bruce Campell can be reached on 571-272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645